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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/711,078	08/20/2004	Stanley Charles Antosh	41260.007	5077

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EXAMINER	
JEAN-LOUIS, SAMIRA JM	
ART UNIT	**PAPER NUMBER**
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/711,078	ANTOSH ET AL.	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This Office Action is in response to the amendment submitted on 12/17/2007. Claims 13-20 are currently pending in the application, with claims 1-12 having being cancelled. Accordingly, claims 13-20 are being examined on the merits herein.

Receipt of the aforementioned amended claims is acknowledged and has been entered.

Examiner also acknowledges amendment of the Abstract and consequently the objection to the Abstract has been withdrawn.

Examiner further acknowledges cancellation of claims 1-12 and consequently the rejection under 35 U.S. C. 112, second paragraph has been withdrawn.

Applicant's argument with respect to Brown's use of soy lecithin, as not being a source of amino acids has been considered but is not found persuasive. Specifically, Brown et al. teaches a basic topical therapeutic application comprising an aqueous solution of 1% copper and a carrier that is suitable for topical application (see detailed description, paragraph 0012, lines 3-6 and paragraph 0022, table). Brown et al. further teaches that the copper basic therapeutic unit may be enhanced by a vasodilator such as 0.3% methylnicotinate (as recited in previously presented claims 1, 5, and 9) and by addition of 2.5% polysorbate-80 (as recited in previously presented claim 2, 6, and 10)

and water (as recited in previously presented claims 3, 7, and 11; see paragraph 0022-table). While Brown et al. does not explicitly teach specific vitamins and amino acids, Brown et al. does however list the addition of granular soy lecithin (see paragraph 0017, line 3) where, according to www.bulkfoods.com/lecithin.htm, granular soy lecithin is a composition of soy flour mixed with lecithin. Furthermore, Iwe et al. and www.soyfoods.com, teach that soy flour is enriched in amino acids including alanine and histidine (see Iwe et al. 2001, table 2) and vitamins B3 or niacin or nicotinic acid (see www.soyfoods.com, pg. 3, table). Brown et al. did not teach a specific percentage of the ingredients, however, Brown et al. did teach that granular soy lecithin is present in low amount (see paragraph 0022) and as a result the amino acids and vitamin percentages would also be in low percentage in the composition. As for the use of Burnett et al., it is being used to teach that liquid composition can include penetration enhancers such as alcohol (which meets the limitation of previously presented claims 4, 8, and 12). Burnett et al. teaches that topical liquid application can comprise a penetration enhancer or solvent such as alcohol. Thus, to one of ordinary skill at the time of the invention would have found it obvious to add alcohol to the composition of Brown et al. containing copper, methyl nicotinate, polysorbate-80, niacin, histidine and alanine for enhanced topical delivery of the aforementioned ingredients. Thus, Brown et al. in view of Burnett et al. render obvious the composition of the instant application as previously presented. Accordingly, the 103 (a) rejection on previously presented claims 1-12 is still maintained.

Applicant's contention that the use of alcohol in the instant invention is for the purpose of enhancing solubility is acknowledged but is not found persuasive. The inclusion of alcohol in applicant's invention for the purpose of enhancing solubility is an intended use and as such is not afforded patentable weight. It is further pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the limitation of the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963).* Thus, the intended use of the alcohol is not afforded patentable weight.

In view of applicant's amendment, the following 102 (b) rejection and the 103 (a) rejections are being made.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention (**see M.P.E.P 608.01 (k)**).

Claim 20 is particularly vague and indefinite given that applicant is claiming a composition wherein said composition is from the group consisting of a liquid and there is no punctuation mark after the word liquid. Moreover, the use of "from the group consisting of" suggests that more than one component is included in said group. Given that applicant did not particularly point out what particular components are encompassed in the group as recited in claim 20, one of ordinary skill in the art would not be able to fully ascertain the metes and bounds of the aforementioned claim.

As a result of the above inconsistencies, the aforementioned claim is unable to be examined as disclosed given that the scope of the claimed subject matter would not be able to be determined by one of ordinary skill in the art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-15 and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Dunnett et al. (WO 98/06278).

Specifically, Dunnett et al. discloses a composition including beta-alanine and creatine, or beta-alanine, L-histidine and creatine or active derivatives thereof (see abstract and pg. 3, lines 28-32). Dunnett et al. further exemplifies his invention as a composition containing about 1-20% beta-alanine, 1-20% L-histidine, 0-60% water (i.e. transdermal carrier) and 39-99% glucose or other simple carbohydrate (instant claims 13-15; see pg. 11, section d, lines 27-31 and pg. 5, lines 11-30 and claims 22-23). The composition of Dunnett et al. can be administered orally, enterally or parenterally (see pg. 10, lines 17-18). Furthermore, the composition of Dunnett et al. can be in solid form or liquid form or the form of suspension if ingested or in liquid form or suspension for infusion into the body (instant claims 17-19; see pg. 11, lines 7-9).

Accordingly, the teachings of Dunnett et al. anticipate claims 13-15 and 17-19.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 16 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Dunnett et al. (WO 98/06278) as applied to claims 13-15 and 17-19 in view of Aschkenasy et al. (U.S. 2005/0020552 A1).

Dunnett et al. does not specifically teach a composition wherein the transdermal carrier is methyl nicotinate.

Aschkenasy et al. teaches a composition for transdermal administration of hormone which includes isostearic acid as a penetration enhancer (see abstract). Aschkenasy et al. further teaches the use of co-enhancers or combination of enhancers such as methyl nicotinate for reducing irritation from the enhancers or from ingredients in the composition (instant claim 16; see pg. 8, paragraph 108-109).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to add methyl nicotinate as disclosed by Aschkenasy et al. into the composition of Dunnett et al. since Aschkenasy et al. teaches the use of methyl nicotinate for reducing irritation from the various ingredients included in transdermal compositions. Given that Dunnett et al. teaches a composition containing beta-alanine, L-histidine, water (i.e. transdermal carrier) and glucose or other simple carbohydrate, and Aschkenasy et al. teaches the use of methyl nicotinate as a co-enhancer for reducing irritation from various ingredients in the composition, one of ordinary skill would have been motivated to add methyl nicotinate as disclosed by Aschkenasy et al.

into the composition of Durnett et al. with the expectation of providing a composition that is non-irritating and efficacious in delivering beta-alanine and histidine to the desired target site.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

03/11/2008

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617